JAN 2 8 2005

K043487
Page 1 of 3

SMDA 510(k) SUMMARY
EVIS EXERA Colonovidoscope XCF Q160W1L/I

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR, Part 807, Subpart E, Section 807.92.

1. GENERAL INFORMATION

Applicant	Aizu Olympus Co., Ltd 500 Aza Muranishi Ooaza Niidera, Monden-machi Aizuwakamatsu-shi, Fukushima, JAPAN 965-8520 Establishment Registration No.: 9610595
Submission Correspondent	Akiko Fukagawa Olympus Medical Systems Corp. (Former name: Olympus Corporation) 2951 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8507, Japan Phone: +81-426-2891 Fax: +81-426-3174 E-mail: akiko_fukagawa@ot.olympus.co.jp Establishment Registration No.: 8010047
Official Correspondent	Laura Storms-Tyler Director, Regulatory Affairs and Quality Assurance Olympus America Inc. Two Corporate Center Drive, Melville, NY 11747-9058 Phone: 631-844-5688 Fax: 631-844-5554 Establishment Registration No.: 2429304

2. Device Identification

Trade Name:	EVIS EXERA Colonovideoscope XCF-Q160W1L/I
Common Name:	Gastrointestinalvideoscope/Colonovideoscope
Regulation Number:	21CFR 876.1500
Regulation Name:	Endoscope and accessories
Class:	II
Product Code:	78 FDF

K043487
page 2 of 3

3. Predicate Device

Predicate Device Name: EVIS EXERA Colonovideoscope CF-Q160AL/I
Manufacturer: Olympus Corporation
510(k) Number: K001241

4. Device Description

The subject devices, EVIS EXERA Colonovideoscope XCF-Q160W1L/I are identical to the predicate device, CF-Q160AL/I, in intended use. These instrument have been designed to be used with an Olympus video system center, light source, documentation equipment, video monitor, endo-therapy accessories such as biopsy forceps and ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, sigmoid colon, colon and ileocecal valve). As for the device specifications, they are basically identical to the predicate devices, the CF-Q160AL/I, with the exception that the subject devices have wider field of views compared to the CF-Q160AL/I/. With this field of view, the XCF-Q160W1L/I may improve the detection of lesions in the colon and has been shown to reduce overall procedure time.

5. Intended Use of the device

This instrument has been designed to be used with the Olympus Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical Unit, Endo-therapy accessories such as a Biopsy Forceps and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, and sigmoid colon, colon, and ileocecal valve).

6. Comparison of Technological Characteristics

Below is the comparison table between the subject devices and predicate device.

Specifications	Subject Device XCF-Q160W1L/I	Predicate Device CF-Q160AL/I
Field of View	170°	140°
Distal end Outer Diameter	ϕ 13.2 mm	ϕ 12.8 mm
Insertion Tube Outer Diameter	ϕ 12.8 mm	ϕ 12.8 mm
Inner Channel Diameter	ϕ 3.7 mm	ϕ 3.7 mm
CCD	253,550 pixels	253,550 pixels

7. Materials

Some of the patient contact materials used in the subject devices are identical to those used in the devices cleared in the past 510(k) submissions. As the others are not identical to the predicate devices, biocompatibility testing was performed in accordance with Japan's Ministry of Health and Welfare notification "GUIDELINES FOR BASIC BIOLOGICAL EVALUATION OF MEDICAL DEVICES" (issued on June 27, 1995), YAKKI No.99.

8. Conclusion

When compared to the predicate device, XCF-Q160W1L/I do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety and effectiveness. Therefore, clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

OLYMPUS AMERICA INC.
c/o Mr. Ned E. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Avenue, SE
GRAND RAPIDS MI 49548

Re: K043487
Trade/Device Name: EVIS EXERA Colonovideoscope XCF-Q160W1L/I
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: 78 FDF
Dated: January 12, 2005
Received: January 13, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K043487

Device Name: EVIS EXERA Colonovideoscope XCF-Q160W1L/I

Indications for Use:
This instrument has been designed to be used with the Olympus Video System Center, Light Source, Documentation Equipment, Video Monitor, Electrosurgical Unit, Endo-therapy Accessories such as a Biopsy Forceps and other ancillary equipment for endoscopy and endoscopic surgery within the lower digestive tract (including the anus, rectum, and sigmoid colon, and ileocecal valve).

Prescription Use ✓ OR Over-The-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043487